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Evaluating the role of graduated compression stockings in the prevention of blood clots in patients who undergo short-stay surgery and who are assessed as being low-risk of developing blood clots

Submission date 25/03/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/03/2022	**Overall study status** Ongoing	
Last Edited 11/03/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Hospital acquired thrombosis is a term used to describe blood clots that may form in the legs and lungs after someone is treated in hospital. A clot in the leg can cause swelling, pain and other long-term problems, such as a leg wound (ulcer). If a clot in the leg breaks off and travels to the lungs, it can cause problems with the lungs' ability to transfer oxygen from the air into the blood and may be life threatening. Having surgery increases a person's risk of developing blood clots. There are a number of reasons for this including being unwell, being unable to move during surgery, and moving around less after surgery. To reduce the chance of a blood clot developing, doctors can give blood-thinning medications and elastic stockings that squeeze the leg muscles.

People having short stay surgery are those who are able to go home the same day or those who stay overnight but go home shortly afterwards. These people are at much lower risk of developing a blood clot than those who stay in hospital for longer. These low-risk people are often given elastic stockings to reduce the chance of developing a blood clot. The risks of wearing the stockings are very low but wearing stockings can be uncomfortable. Occasionally some people with poor blood supply to their feet, can develop wounds on one or both of their feet after wearing elastic stockings, but this is rare.

In the UK, there are over a million short stay surgeries performed each year and most of these people are given elastic stockings to wear. Collectively, these elastic stockings cost the NHS a lot of money and it remains unknown if they benefit these people.

A recent study in a different group of people, who are at higher risk of developing a blood clot and are usually given blood-thinning medications, showed that elastic stockings offered no additional benefit compared to just having blood-thinning medications alone. There are

currently no up to date studies specifically in this group of people that look at whether these elastic stockings reduce the chance of developing a blood clot.

The purpose of this study is to investigate if it is worthwhile to continue using elastic stockings in people having surgery where the risk of developing blood clots is low.

Who can participate?
People enrolled in the study will be over the age of 18 and scheduled to undergo a surgical procedure with a hospital stay less than 48 hours. All participants will be checked for their risk of blood clots when they arrive in hospital for surgery. This study will only include people where the check shows a low risk of developing blood clots, which will be assessed using a nationally recognised tool.

What does the study involve?
At random, participants will be given elastic stockings to wear during their time in hospital or not given elastic stockings at all. The surgery itself and all other processes will continue as normal.

Participants will be contacted (by telephone, email or SMS) at 7 days and 90 days after their surgery to see how they are getting on and to see if they developed a blood clot. Participants will be provided with information on the signs and symptoms of blood clots, such as a swollen painful leg. They will be advised to attend the emergency department if they develop any of the signs and symptoms, and not wait for the follow-up to avoid delay. If the doctors and nurses suspect a participant has developed a blood clot, they will come to hospital for extra tests and treatment which is best practice if a blood clot is suspected.

What are the possible benefits and risks of participating?
Possible benefits: Participants will receive increased education around VTE prevention (i.e. via the ‘Signs and Symptoms of a blood clot’ leaflet). Both patients and the health service stand to benefit from evidence to support the safe rationalisation of the use of GCS as a health technology.
Possible risks: The risks associated with graduated compression (GCS) use are low, particularly in this patient cohort where the expectation is to wear the stockings for a short period of time (i.e. from the time of surgery until ambulant [which may be as short as a few hours and no longer than 48-hours]). GCS may cause skin irritation and itching. Patients will be advised to speak to their healthcare professional at any point prior to (and indeed after) discharge should they have any concerns. Individuals with a contraindication to wearing GCS will not be included. The relevant participants will also be followed up at 7-days post procedure and information about any adverse events associated with GCS will be captured. We do not expect participation to result in any additional burden on the participant. Participants will be followed-up remotely at 7 and 90-days post-surgical procedure. Data can be provided via online survey, SMS or telephone depending on patient preference. Minimal data collection will occur at these follow-ups (i.e. only self-reported VTE outcome data, the short 5-item EQ-5D questionnaire and information on adverse events associated with GCS [if applicable] is collected at 7-days. At 90-days, only self-reported VTE outcome, the EQ-5D and the resource use questionnaire data is collected).

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
March 2022 to December 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
1. Sarrah Peerbux (public contact), s.peerbux@imperial.ac.uk
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Study website
https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/pets-trial/

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312752

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 312752, NIHR133776

Study information

Scientific Title
Examining the benefit of graduated compression stockings in the Prevention of vEnous Thromboembolism in low-risk Surgical patients: a multicentre cluster randomised controlled trial (PETS Trial)

Acronym
PETS

Study objectives
The principal objective of this study is to evaluate the potential benefit of GCS in the prevention of VTE in patients undergoing short-stay surgical procedures, assessed as being at low-risk for VTE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2022, London - Camden and King's Cross REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 1048089; camdenandkingscross.rec@hra.nhs.uk), ref: 22/LO/0390

Study design
Multicentre cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prevention of venous thromboembolism (VTE) in patients who are deemed to be at low-risk of developing VTE and who undergo day-case/short-stay surgical procedures.

Interventions
This is a cluster-designed RCT in which study centres will either be randomised to intervention or control.

Centres randomised to the intervention arm, which is the current standard of care, will consist of participants receiving graduated compression stockings (GCS). Clinical staff (e.g. preassessment or theatre support workers) will issue stockings to all patients who are scheduled to undergo short-stay surgery. Participants will be instructed to wear their stockings just before undergoing the surgical procedure and to remove the stockings as soon as they are ambulant (i.e. after the procedure).

In those centres randomised to the control arm, participants will not receive graduated compression stockings.

Intervention Type
Behavioural

Primary outcome measure
Self-reported VTE within 90-days of short-stay surgical procedure.

Secondary outcome measures
1. Mortality measured using patient notes and SAE log review at 7 and 90-days
2. Cost-Effectiveness Ratio measured using the Incremental Cost-Effectiveness Ratio (ICER) at 90 days
3. Generic Quality of life (as measured by the EQ-5D) at 7 and 90-days
4. Adverse events with GCS (at 7-days, for participants enrolled in the site randomised to the 'stockings' cluster only) measured using patient records

Overall study start date
25/03/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Adults (18-59 years of age) scheduled to undergo a surgical procedure with a hospital stay <48 hours
2. Individuals assessed as being at low-risk of developing VTE as per the DHRA tool i.e. no assessed thrombosis risk factors / scoring 0

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
Both

Target number of participants
21472

Total final enrolment
11321

Key exclusion criteria
Current exclusion criteria as of 12/09/2024:
1. Individuals with a contraindication to GCS
2. Individuals assessed as being at moderate or high risk of VTE as per the DHRA tool
3. Individuals requiring therapeutic anticoagulation
4. Individuals requiring pharmacological prophylaxis
5. Individuals with thrombophilia/ thrombogenic disorder
6. Individuals with a previous history of VTE
7. Individuals requiring intermittent pneumatic compression therapy beyond theatre and recovery
8. Female patients of childbearing age who have a positive pregnancy test
9. Individuals with lower limb immobilisation
10. Inability to provide informed consent

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Previous exclusion criteria as of 14/08/2023 to 12/09/2024:
1. Individuals with a contraindication to GCS
2. Individuals assessed as being at moderate or high risk of VTE as per the DHRA tool
3. Individuals requiring therapeutic anticoagulation
4. Individuals with thrombophilia/ thrombogenic disorder
5. Individuals with a previous history of VTE
6. Individuals requiring intermittent pneumatic compression therapy beyond theatre and recovery
7. Individuals requiring extended thromboprophylaxis beyond discharge
8. Female patients of childbearing age who have a positive pregnancy test
9. Individuals with lower limb immobilisation
10. Inability to provide informed consent
11. Individuals requiring pharmacological prophylaxis

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Previous exclusion criteria:
1. Individuals with a contraindication to GCS
2. Individuals assessed as being at moderate or high-risk of VTE as per the DHRA tool
3. Individuals requiring therapeutic anticoagulation
4. Individuals with thrombophilia/ thrombogenic disorder
5. Individuals with a previous history of VTE
6. Individuals requiring intermittent pneumatic compression therapy beyond theatre and recovery
7. Individuals requiring extended thromboprophylaxis beyond discharge
8. Female patients of childbearing age who have a positive pregnancy test
9. Individuals with lower limb immobilisation
10. Inability to provide informed consent.

Date of first enrolment
08/09/2022

Date of final enrolment
18/11/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
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Westbury-on-trym
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BS10 5NB

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
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SM5 1AA

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Hull University Teaching Hospitals NHS Trust
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Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
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NG7 2UH

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
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SE1 9RT

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University Hospitals of Leicester NHS Trust
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Mid and South Essex NHS Foundation Trust
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SS0 0RY

Study participating centre
Cardiff & Vale University Health Board
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CF14 4XW

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
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United Kingdom
DN2 5LT

Study participating centre
Portsmouth Hospitals University NHS Trust
United Kingdom
PO6 3LY

Study participating centre
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Sponsor type
University/education

Website
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ROR
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Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This trial will provide evidence to guide widespread clinical practice and will facilitate an update of national and international guidelines. If the trial were to find that GCS offered no benefit, then providers would recommend against their use. This would prevent patients receiving unnecessary GCS and the lead to a subsequent re-allocation of resources which is estimated to be as much as £23.3 million per annum. We anticipate that this trial will inform NICE guidelines alongside publication in a high-impact journal, presentation at international conferences and dissemination on the Imperial College London, NIHR and Thrombosis UK websites and other media streams.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
Data sharing statement to be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	18/07/2022	13/10/2022	No	No
Protocol article		17/01/2023	19/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	29/11/2022	14/08/2023	No	No
Protocol file	version 7.0	07/05/2024	12/09/2024	No	No